

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

**METACEL PHARMACEUTICALS, LLC,**

*Plaintiff,*

v.

**RUBICON RESEARCH PRIVATE  
LIMITED,**

*Defendant.*

Civil Action No. 2:21–CV-19463-EP-JRA

Motion Return Date: Sept. 6, 2022

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**PLAINTIFF’S BRIEF IN OPPOSITION TO DEFENDANT’S MOTION FOR  
LEAVE TO MOVE FOR SUMMARY JUDGMENT**

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Plaintiff, Metacel Pharmaceuticals, LLC, opposes Defendant Rubicon Research Private Limited's ("Rubicon") Motion for Leave to Move for Summary Judgment of Non-infringement. Rubicon's motion is an improper filing because it violates the Court's directives issued during the parties' initial scheduling conference and the Pretrial Scheduling Order governing this case (Dkt. No. 25). Consequently, the Court should summarily deny Rubicon's motion for leave.

### **BACKGROUND**

This is an action for patent infringement under 35 U.S.C. § 271 filed by Metacel in response to Rubicon's filing of Abbreviated New Drug Application ("ANDA") No. 214445 with the Food and Drug Administration ("FDA"). Rubicon's ANDA seeks approval to commercially market a generic version of Metacel's branded Ozobax® baclofen oral solution 5mg/5mL ("ANDA Product") prior to the expiration of United States Patent No. 10,610,502 (the "'502 Patent" or "Patent-in-Suit") owned by Metacel. Generally, the Patent-in-Suit claims a method for relaxing muscles or treating spasticity by administering a baclofen oral solution, including certain additional steps regarding determination of an impurity and storage of the oral solution. Rubicon denied the material allegations of Metacel's complaint and asserted various affirmative defenses. (Dkt. Nos. 1, 7).

The parties are also preparing the Joint Claim Construction and Prehearing Statement, currently due to be filed on August 24, 2022. Other than its ANDA filing

produced at the outset of this litigation, Rubicon has **not produced a single document** in response to Metacel's requests for production of documents served on May 6, 2022. Declaration of Matthew D. Zapadka ("Decl." ¶ 8). Rubicon instead seeks to prematurely attempt to move for summary judgment in spite of its minimal participation in discovery and refusal to produce certain samples as of the date of this filing. At this time, discovery is ongoing, including attempts to resolve Rubicon's failure to date to produce requested sample materials for Metacel to test.

The parties dispute the construction of the following term in the '502 patent: "a buffer comprising citric acid, a salt of citric acid, or any combination thereof." *Id.* ¶ 6. Although the parties have exchanged extrinsic and intrinsic evidence, no depositions related to claim construction or otherwise have taken place, no *Markman* briefing has occurred, and no determinations have been made as to the underlying factual issues of that disputed claim term. *Id.* ¶ 7. Multiple material factual and legal issues remain unresolved in this case and Rubicon's violative motion for leave must be denied.

## ARGUMENT

### **I. Rubicon's Motion For Leave Is Procedurally Improper Because it Does Not Abide by Judge Hammer's Directive at the Rule 16 Conference and Improperly Attaches a Motion for Summary Judgment.**

At the March 24, 2022, Scheduling Conference, Magistrate Judge Hammer made it clear to the parties that any request for leave to move for summary judgment

on non-infringement requesting a prehearing conference must be submitted by way of a joint letter. The Court instructed that:

Any request for leave to move for summary judgment on noninfringement may be -- and this is a request -- oh, and I should add, it doesn't need to be a formal motion. **In fact, you guys are going to submit any such request by way of a joint letter.** It's just, especially in a time-sensitive case like this, far more efficient where each side sets forth its position, limited to -- I don't know -- five double-spaced pages per side. Okay?

(Dkt. No. 23 at 14:10-23 (Transcript, Mar. 24, 2022; emphasis added)). Rubicon failed to follow the Magistrate Judge's directive, did not coordinate with Metacel to meet and confer regarding preparation and submission of the required joint letter, and did not give any notice whatsoever that Rubicon intended to imminently file its motion for leave.

Rubicon's Motion for Leave to Move for Summary Judgment also violates the Court's Pretrial Scheduling Order governing this case (Dkt. No. 25) and is prejudicial to Metacel. This Court's General Pretrial and Trial Procedures § II(E)(i) provide that: "Except as permitted by Local Rule 12.1, no formal motions may be filed without leave of Court."<sup>1</sup> There was no attempt to meet and confer with Metacel's counsel prior to the filing of Rubicon's motion for leave or any effort to discuss the necessary joint letter, which was required by the Court under the

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<sup>1</sup> On June 27, 2022, this case was reassigned to Judge Padin.

procedure set forth below. In addition, the Pretrial Scheduling Order expressly provides that:

No motions are to be filed without prior written permission from this Court. All dispositive motions must first be subject to a dispositive motion pre-hearing. Discovery must be completed prior to the filing of a dispositive motion. These prerequisites must be met before any motions are filed and the motions will be returned if not met. All calendar or dispositive motions if permitted, shall comply with Local Civil Rules 7.1(b) and 56.1.

(Dkt. No. 25 ¶ 34 (emphasis in original)). That Order also expressly stated that “[a]ny request for leave to move for summary judgment on non-infringement” may not be filed before July 18, 2022 and that “[d]ispositive motions, in any, are to be filed by leave of Court only....” (Dkt. No. 25 ¶¶ 35, 36).

Rubicon’s surprise motion was filed after the parties submitted status letters to this Court and two days after participating in the Court’s status conference. At the conference, Rubicon failed to inform the Court and Plaintiff that it intended not to file a joint letter as the Court had directed, and failed to inform the Court that they intended to file a formal motion for leave, while also attaching a full-blown motion for summary judgment that had not yet been authorized by the Court. (*See*, Dkt. Nos. 38 and 39).

Rubicon’s attaching of its motion for summary judgment to its motion for leave improperly attempts to obtain the Court’s consideration of its summary judgment motion. (Dkt. Nos. 39-41). Rubicon’s submission is impermissible under

this Court's procedures and it was wrong for Rubicon to believe such liberties could be taken in light of the Court's directives and orders. Not only did Rubicon ignore the Court's rules, Scheduling Order, and directive from the Initial Scheduling Conference, but Rubicon chose not to follow this Court's rules for filing a summary judgment motion that could be considered by the Court, or even requesting the right to do so in advance. (*See* Dkt. No. 41)."<sup>2</sup>

Instead, Rubicon did exactly what this Court said **not** to do when it attached its purported complete motion for summary judgment with its motion for leave. Rubicon's filing of its complete motion for summary judgment and supporting evidence makes its request for leave procedurally improper. Rubicon's filing of a violative motion for leave (not a joint letter or any process that resembles the Court's direct instructions and order in this case) that also attaches a substantive dispositive motion with supporting materials render Rubicon's application a nullity.

If the Court were to consider such a procedurally improper application, it would result in Rubicon avoiding pretrial obligations, including: (i) production of documents and information responsive to written discovery requests; (ii) production

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<sup>2</sup> There are a number of reasons why Rubicon's motion for summary judgment is insupportable. Metacel respectfully reserves its right to respond to Rubicon's motion for summary judgment when and if it is properly filed and consistent with this Court's rules and procedures. For the avoidance of doubt, Metacel's opposition to the motion for leave is not an admission or waiver that anything in Rubicon's summary judgment materials are factually or legally correct.



of samples of materials requested by Metacel for months so it can conduct proper testing of the accused product; and (iii) the construction of an important claim term in dispute, which has not been briefed or considered by the Court. In light of the present status of this case and the early stages of discovery, Metacel respectfully submits that summary judgment should not be authorized or filed until the thirty-day period after a ruling on claim construction as contemplated by the Court and expressly discussed during the original scheduling conference. Accordingly, for at least the foregoing the reasons, the Court should deny Rubicon's motion for leave.

## **II. Rubicon's Motion for Leave Fails Based on the Arguments Previewed in That Motion.**

Even assuming Rubicon had followed proper procedures and not violated the Court's directive and Scheduling Order, its application would need to be seen in the greater context of pretrial proceedings in order to evaluate its propriety. Rubicon's raw material and intermediate product samples have become an issue in the case, and we have attempted to meet and confer with Rubicon for months—as early as April 2022—to obtain production of such samples, including raw materials and intermediate products, but they have yet to be produced. *See, e.g.*, Dkt. No. 37 at 2 (Letter to Judge Padin dated July 22, 2022) (“The parties are meeting and conferring regarding Metacel's request for production of samples of raw materials and intermediate product, but this issue is not yet ripe for Court consideration.”). This issue may be presented to Your Honor, but the fact of its existence is an issue that

must be considered in the context of Rubicon's procedural failure. In addition, the parties continue to engage regarding Rubicon's document production. *See Dowling v. City of Philadelphia*, 855 F.2d 136, 139 (3d Cir. 1998) ("The court is obliged to give a party opposing summary judgment an adequate opportunity to obtain discovery."); *Smith v. Director's Choice, LLP*, No. 15-81, 2018 WL 1509081, at \*5 (D. N.J. 2018); *see also* Local Civil Rule 1.1(b).

Claim construction issues also exist. The parties dispute the meaning of the claim term "a buffer comprising citric acid, a salt of citric acid, or any combination thereof." Decl. ¶ 6. In the ordinary course, claim construction issues would be resolved prior to any court deciding motion for summary judgment. Indeed, new claim construction issues have arisen in the case, which we respectfully reserve to raise if not otherwise resolved by the parties' further meet and confer efforts.

Rubicon's counsel represented to Magistrate Judge Hammer at the Scheduling Conference on March 24, 2022, that Rubicon would not seek leave for an early summary judgment motion if claim construction was needed:

And what we likely believe in this -- in this schedule where we're requesting an early motion for summary judgment, even before claim construction, what we likely believe is that there won't be any claim construction needed for us to make our case for summary judgment.

If we assess it, after seeing their infringement contentions and we realize that there has to be a claim construction, we won't ask for permission to move for summary judgment at that point in time. We just want the opportunity to be able to do so if we conclude, as we think we conclude now, that once we see all their contentions, we see what

they've done with our samples, and if there's anything left to be tried, then we won't move for summary judgment. We won't ask for permission to move for summary judgment. But if we're right, then we want it in the schedule early. And that's why it's here.

(Dkt No. 23 ¶¶ 11:20-12:10.) In response, the Court's Scheduling Order included the provision allowing Rubicon to seek leave to file a summary judgment motion so long as the Court's criteria were satisfied. (Dkt. No. 25 ¶ 35).

Now, Rubicon wants permission to file a dispositive motion **and** wants to contest the construction of a key claim term along with creating additional claim construction issues without following this Court's procedures for either. The Court should not entertain Rubicon's attempts to circumvent this Court's procedures. Consequently, this Court should deny Rubicon's motion for leave as failing to establish a basis that it would likely prevail on summary judgment.

### **CONCLUSION**

For the foregoing reasons, Rubicon's Motion for Leave to Move for Summary Judgment is procedurally improper and meritless, and accordingly for the foregoing reasons, the Court should deny Rubicon's application.

Dated: August 23, 2022

Respectfully submitted,

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